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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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NORRIS, MCLAUGHLIN & MARCUS
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,672	DETTMAR ET AL.	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 20, 2009 with the addition of newly added Claim 21.

Any rejection or objection not repeated is hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-14 and 16-21 are under examination.

Response to Arguments

Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

The metes and bounds of Claim 21 are made uncertain by the phrase, "wherein said composition is in a form so that in use it is dispersed in a liquid prior to ingestion", which follows the period appearing at the end of the sentence of the claim. Since the phrase is separated from the claim language of Claim 21 by a period, it is unclear as to whether Applicant intends for other limitations, such as encompassed by the aforementioned phrase, to follow the claimed subject matter. Applicant is reminded that claim must be only one sentence long and should be numbered.

Claim Rejections - 35 USC § 102

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Palkhiwala (US 6,361,799 B1), made evident by Al-Assaf et al. (AE; WO 01/85190 A1). Newly applied as necessitated by amendment.

Applicant claims an ingestible composition consisting essentially of ispaghula, colloidal silica, and an ingestible surfactant wherein the surfactant is a polyoxyethylene sorbitan fatty acid ester and is present in an amount of between 1 w% and 2wt% of the total weight of the ingestible composition.

Palkhiwala teaches an ingestible composition comprising psyllium or ispaghula (Please note that ispaghula and psyllium are interchangeable terms used in the art referring to powdered psyllium seed husk or powdered psyllium. For instance, Al-Assaf et al. teaches, "Ispaghula is sometimes referred to as psyllium", on page 1, line 7.), colloidal silica, and an ingestible surfactant, namely Polysorbate 80 (TWEEN™) in granular or particular form, and a method of making thereof, wherein the amounts of the claim-designated ingredients (colloidal silica and surfactant) are one and the same as recited in Claims 5 and 13. *See* Column 7, line 10 bridging Column 7, line 25, wherein Palkhiwala teaches combining Polysorbate-80 with psyllium in the absence of a solvent, granulating agent or polyvinyl pyrollidone. Palkhiwala teaches that the process provides for the making of a powder that disperses readily in water without clumping. The amount of surfactant used in the process is in the range of from about 0.05 to 1.5 percent by weight, based on the total weight of the composition, and are selected from

sorbitan esters and polyoxyethylene sorbitan fatty acid esters, such as polyethylene 20 sorbitan monooleate or Polysorbate-80.

Please note that AEROSIL™ is the colloidal silica comprising the Palkhiwala' composition; therefore, a colloidal silica having a particle size of between 5nm and 5μm and a specific surface area between 50 and 400gm^2 is inherent to the prior art composition, as readily admitted by Applicant on page 6 of the specification, in its entirety.

While the rejection herein is newly a applied, the Examiner notes that Applicant argues that Palkiwala fails to teach the use of irradiated isphagula in any part of his specification, or amongst his examples. Thus, Applicant asserts that the Examiner fail to meet the proper burden of proof based on "anticipation" type rejection under 35 USC 102(b). While fully considered, this is not persuasive because the scope of the subject matter set forth in Claim 21 does not encompass "irradiated ispaghula".

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 9-11, 13, 14 and 16-20, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Palkhiwala (US 6,361,799 B1) in view of Al-Assaf et al. (AE; WO 01/85190 A1). Newly applied as necessitated by amendment.

Applicant claims an ingestible composition comprising irradiated ispaghula colloidal silica, and art ingestible surfactant wherein said composition is in a form so that in use it is dispersed in a liquid prior to ingestion. Applicant further claims an ingestible composition according to claim 1 wherein said composition is in particulate or granular form; wherein the silica has a particle size of between 5nm and 5μm; wherein the silica

has a specific surface area of between 50 and 400 m^2/gm; wherein the silica is present in an amount of between 0.01wt% and 5wt% of the total weight of the ingestible composition; wherein the ingestible surfactant is a polyethylene-, polypropylene-, or polyoxyethylene- based surfactant. Applicant further claims an ingestible composition according to claim 6 wherein the polyoxyethylene-based surfactant is a polyoxyethylene sorbitan fatty acid ester; and, wherein the surfactant is a polyoxyethylene monostearate or a glycerol polyethylene glycol oxystearate. Applicant further claims an ingestible composition according to claim 1 wherein the ingestible surfactant is present in an amount of between 0.01wt% and 5wt% of the total weight of the ingestible composition. Applicant further claims an ingestible composition according to claim 11 wherein the ingestible surfactant is polyethylene glycol and is present in an amount of between 0. I wt% and 2wt% of the total weight of the ingestible composition; and, wherein the surfactant is a polyoxyethylene sorbitan fatty acid ester and is present in an amount of between 1 wt% and 2wt% of the total weight of the ingestible composition.

Applicant claims a method of making an ingestible composition comprising irradiated ispaghula, colloidal silica, and an ingestible surfactant, the method comprising a step of blending the ispaghula with the colloidal Silica and the ingestible surfactant. Applicant further claims a method according to claim 14, of making an ingestible composition comprising ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant without the employment of any solvent. Applicant further claims a method according to claim 16, of making an ingestible composition comprising

irradiated ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant without the employment of isopropyl alcohol. Applicant claims a method according to claim 14, of making an ingestible composition comprising irradiated ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant without the employment of any granulating agent. Applicant further claims a method according to claim 18, of making an ingestible composition comprising irradiated ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible without the employment of polyvinyl pyrotlidone. Applicant further claims a method according to claim 14, of making an ingestible composition comprising irradiated ispaghula, colloidal silica, and an ingestible surfactant, the method comprising the step of blending the ispaghula with the colloidal silica and the ingestible surfactant without the employment of any solvent; and without the employment of any granulating agent.

Palkhiwala teaches an ingestible composition comprising psyllium or ispaghula (Please note that ispaghula and psyllium are interchangeable terms used in the art referring to powdered psyllium seed husk or powdered psyllium. For instance, Al-Assaf et al. teaches, "Ispaghula is sometimes referred to as psyllium", on page 1, line 7.), colloidal silica, and an ingestible surfactant, namely Polysorbate 80 (TWEEN™) in granular or particular form, and a method of making thereof, wherein the amounts of the claim-designated ingredients (colloidal silica and surfactant) are one and the same as

recited in Claims 5 and 13. *See* Column 7, line 10 bridging Column 7, line 25, wherein Palkhiwala teaches combining Polysorbate-80 with psyllium in the absence of a solvent, granulating agent or polyvinyl pyrollidone. Palkhiwala teaches that the process provides for the making of a powder that disperses readily in water without clumping. The amount of surfactant used in the process is in the range of from about 0.05 to 1.5 percent by weight, based on the total weight of the composition, and are selected from sorbitan esters and polyoxyethylene sorbitan fatty acid esters, such as polyethylene 20 sorbitan monooleate or Polysorbate-80. With regard to the claim limitation of each of Claim 3 and Claim 4, AEROSIL™ is the colloidal silica comprising the Palkhiwala' composition; therefore, a colloidal silica having a particle size of between 5nm and 5μm and a specific surface area between 50 and 400gm^2 is inherent to the prior art composition, as readily admitted by Applicant on page 6 of the specification, in its entirety. The teachings of Palkhiwala, as set forth above, teach the instantly claimed composition and method of making thereof except for wherein the ispaghula is an irradiated ispaghula.

Al-Assaf teaches an ingestible composition comprising irradiated ispaghula in the making of an ingestible composition comprising irradiated ispaghula which is used in the making of pharmaceuticals in a particulate solid form intended to be mixed in water prior ingestion. *See* patent claims 1-9. Al-Assaf teaches that irradiation of ispaghula effectively kills foreign biological matter such as insects and microorganisms entrapped in the plant material; and, thus exposure of ispaghula to a dose of radiation renders a sterilized ingestible ispaghula composition that is safe for the making of products

intended for human consumption. Al-Assaf further teaches that the irradiation appears to improve the water retention characteristics of ispaghula, as well as improve the capability of ispaghula to absorb water in the gut after ingestion. *See* page 2, lines 18-27. Thus, it was known at the time of the invention that irradiation of ispaghula was useful in the making of ingestible compositions fit for human consumption and useful in the making of pharmaceuticals, such as the bulk laxatives comprising ingestible psyllium and having a form so that in use it is dispersed in a liquid prior to ingestion as taught by Palkhiwala. Therefore, an artisan of ordinary skill would have had a reasonable expectation that using an irradiated ispaghula, such as the irradiated ispaghula taught by Al-Assaf, to optimize the composition and method of making of making thereof taught by Palkhiwala would be successful. This reasonable expectation of success would have motivated the artisan to irradiate the psyllium used in the method of making of the composition taught by Palkhiwala or to replace the psyllium used to prepare the composition in the method taught by Palkhiwala with the ingestible irradiated ispaghula taught by Al-Assaf to arrive the instantly claimed inventions because to do so would provide the means of producing a sterilized ingestible composition comprising a natural plant material known for its usefulness in the making of therapeutic compositions intended to be imbibed or consumed by humans and having improved water absorption capability.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition and the claimed manufacture thereof are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant argues, "Palkhiwala fails to teach or suggest the use of irradiated isphagula in any part of his specification, or amongst his examples." Thus, Applicant presumes that the "Examiners rejection of the claims is in no small part based on a "hindsight reconstruction" of the applicant's claimed invention wherein there lacks an appropriate teaching or suggestion." In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 1-8, 11, 12 and 14, and 16-20, as amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Halow (US 5,710,183) in view of Palkhiwala (US 6,361,799 B1) and Al-Assaf et al. (AE; WO 01/85190 A1). Newly applied as necessitated by amendment.

Applicants claimed invention of Claims 1-6, 11, 14 and 16-20 was set forth above. Applicant further claims an ingestible composition according to claim 6 wherein the polyethylene-based surfactant is a polyethylene glycol. Applicant further claims an ingestible composition according to claim 7 wherein the polyethylene glycol has a molecular weight of between 200 and 40,000.

Halow teaches combining polyethylene glycol (molecular weight of between 200 and 40,000) with psyllium husk seed powder (also known in the art as ispaghula)) to provide a particular or granular ingestible composition prepared without employment of any solvent, isopropyl alcohol, granulating agent or polyvinyl pyrollidone. The composition taught by Halow is liquid-dispersible.

The teachings of Halow are set forth above. Hallow teaches the instantly claimed invention except for colloidal silica. However, it would have been obvious to one of ordinary skill in the art to combine the claim-designated ingredient to the teachings of Halow to provide the instantly claimed invention because Palkhiwala taught AEROSIL™ as a conventional excipient used in processes for formulating a powder bulk laxative composition involving mixing psyllium powder with a surfactant to provide a uniform coating thereto, as taught by Halow. Given the combined teachings as a whole, one of ordinary skill in the art would have been motivated and one would have had a

reasonable expectation of success to add colloidal silica to the Halow' teachings to arrive the claimed inventions because at the time the invention was made Palkhiwala taught that adding AEROSIL™ to a surfactant coated psyllium powder provided for the making of an ingestible powder that disperses readily in water without clumping. Furthermore, it is well known in the art of pharmaceutical production that glidants, such as the colloidal silica taught by Palkhiwala, enhance the flow of a granular mixture by reducing interparticle friction. The combined teachings of Halow and Palkhiwala, as set forth above, teach the instantly claimed composition and method of making thereof except for wherein the ispaghula is an irradiated ispaghula.

Al-Assaf teaches an ingestible composition comprising irradiated ispaghula in the making of an ingestible comprising irradiated ispaghula which used in the making of pharmaceuticals in a particulate solid form intended to be mixed in water prior ingestion. *See* patent claims 1-9. Al-Assaf teaches that irradiation of ispaghula effectively kills foreign biological matter such as insects and microorganisms entrapped in the plant material; and, thus exposure of ispaghula to a dose of radiation renders a sterilized ingestible ispaghula composition that is safe for the making of products intended for human consumption. Al-Assaf further teaches that the irradiation appears to improve the water retention characteristics of ispaghula, as well as improve the capability of ispaghula to absorb water in the gut after ingestion. *See* page 2, lines 18-27. Thus, it was known at the time of the invention that irradiation of ispaghula was useful in the making of ingestible compositions fit for human consumption and useful in the making of pharmaceuticals, such as the bulk laxatives comprising ingestible ispaghula and having

a form so that in use it is dispersed in a liquid prior to ingestion, as taught by the combined teachings of Halow and Palkhiwala. Therefore, an artisan of ordinary skill would have had a reasonable expectation that using an irradiated ispaghula, such as the ingestible irradiated ispaghula taught by Al-Assaf, to optimize the composition and method of making of making thereof taught by the combined teachings of Hallow and Palkhiwala would be successful. This reasonable expectation of success would have motivated the artisan to irradiate the ispaghula used in the method of making of the composition taught by the combined teachings of Halow and Palkhiwala or to replace the ispaghula used to prepare the composition in the method taught by the combined teachings of Halow and Palkhiwala with the ingestible irradiated ispaghula taught by Al-Assaf to arrive the instantly claimed inventions because to do so would provide the means for the making of a sterilized ingestible composition comprising a natural plant material known for its usefulness in the making of therapeutic compositions intended to be imbibed or consumed by humans and having improved water absorption capability, despite Applicant's arguments to the contrary.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

As each of the references indicate that the various proportions and amounts of the ingredients used in the claimed composition and the claimed manufacture thereof are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant asserts that any rejection of the claims applying either Palkhiwala alone or in combination with Halow. "is in no small part based on a "hindsight reconstruction" of the applicant's claimed invention wherein there lacks an appropriate teaching or suggestion." In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at http://www.uspto.gov/ebc/index.html or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michele Flood
Primary Examiner
Art Unit 1655

MCF
May 9, 2009

/Michele Flood/
Primary Examiner, Art Unit 1655